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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/815,820

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David Walter Wright

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EXAMINER

BOWERS, NATHAN ANDREW

ART UNIT

PAPER NUMBER

1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/815,820	Applicant(s) WRIGHT ET AL.	
	Examiner NATHAN A. BOWERS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25, 28-33 and 36-47 is/are pending in the application.
- 4a) Of the above claim(s) 25, 28-33 and 36-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

Art Unit: 1797

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 2, 4-6, 10-15 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Owen (WO 00/18226) in view of Barbera-Guillem (US 20040029266) and Hassanein (US 6953655).

With respect to claims 1, 3, 5, 9, 10, 12-15 and 18-24, Owen discloses an apparatus for holding an organ comprising a portable housing (Figure 2:65) and an organ support surface (Figure 2:66) designed to support the organ within the housing. Pages 7-10 indicate that a perfusion system is provided such that fluids are added to and removed from the housing using tubing in communication with openings positioned across the housing. The portable housing further comprises a closable air vent (Figure 11D:61) that functions as a pressure control valve capable of regulating pressure within the housing. Owen, however, does not expressly indicate that the vent is configured to restrict the rate at which external pressure changes are transmitted to the inside of the portable housing.

Barbera-Guillem discloses a cell culture chamber in which a membrane (Figure 1:180) is provided for regulating gas diffusion to and from the interior of the chamber. Paragraph [0204] teaches that the membrane is fluid impervious and gas permeable. Paragraph [0207] states that the membrane is formed from a material capable of regulating the rate of gas diffusion regardless of the pressure of the gases in the external atmosphere.

Owen and Barbera-Guillem are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to equip the portable housing disclosed by Owen with a membrane material capable of restricting the rate at which external pressure changes are transmitted to the inside of the portable housing. Barbera-Guillem teaches that cell cultures are sensitive to changes in pressure and the concentration of critical gases. Accordingly, it would have been obvious to allow pressure to vary within the housing of Owen to between predetermined values known to be compatible with tissue storage. Furthermore, it would have obvious to provide the vent of Owen with a membrane capable of regulating the rate of gas diffusion regardless of the pressure of the gases in the external atmosphere.

The combination of Owen and Barbera-Guillem still differs from Applicant's claimed invention because Owen does not expressly state that more than one lid forms an airtight seal with the portable housing.

Hassanein discloses a device for storing and maintaining a tissue. The system includes a portable housing (Figure 2:20) sealed by a first lid (Figure 2:102) and a second lid (Figure 2:104). This is disclosed in column 10, line 66 to column 11, line 22. Hassanein teaches that both the first lid and the second lid each form a seal with the portable housing using a clamping ring (Figure 2:96).

Owen and Hassanein are analogous art because they are from the same field of endeavor regarding organ perfusion, storage and transport devices.

At the time of the invention, it would have been obvious to provide the Owen apparatus with first and second lids that are each include a pressure control valve, and are each capable of forming an airtight seal with the portable housing. The use of an additional lid would prove desirable because it would serve to discourage contamination by providing an additional barrier. Hassanein indicates that it is known in the art to utilize multiple lids comprising ports designed to interact with one another. As evidenced by Hassanein, one of ordinary skill in the art would have been able to use multiple lids to create an airtight seal with the portable housing of an organ perfusion device, such as that of Owen, in a highly predictable manner using well known techniques.

With respect to claim 2, Owen, Barbera-Guillem and Hassanein disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. Although Owen only describes the use of a single pressure control valve per lid, it would have been obvious to utilize a plurality of closeable vents per lid in this device. The addition of extra venting mechanisms would involve no major structural reconfiguration of the Owen device, and would require only a minor duplication of parts that are well known in the art. See MPEP 2144.04. Additional pressure control valves would result in a more uniform removal of gases from the organ maintenance system.

With respect to claims 4 and 11, Owen, Barbera-Guillem and Hassanein disclose the apparatus in claims 1 and 9. Owen further states that the portable housing includes

Art Unit: 1797

a lid and the pressure control valve is arranged in the lid. This is apparent from Figure 11D.

With respect to claim 6, Owen and Barbera-Guillem disclose the apparatus in claim 1 wherein the portable housing further comprises a pressure sensor that is referenced to a desired pressure. Page 11 of Owen states that a pressure sensor (Figure 2:P1) is used to control the pressure of medical fluid fed into an organ.

2) Claims 1, 2, 4-6, 10-15 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahy (US 5586438) in view of Barbera-Guillem (US 20040029266) and Hassanein (US 6953655).

With respect to claims 1, 3, 5, 9, 10, 12-15 and 18-24, Fahy discloses an apparatus for holding an organ comprising a portable housing (Figure 1:11) and an organ support surface (Figure 1:13) designed to support the organ within the housing. Column 4, line 63 to column 5, line 49 indicate that a perfusion system is provided such that fluids are added to and removed from the housing using tubing in communication with openings positioned across the housing. See also Figure 2. Column 4, lines 1-6 state that the portable housing further comprises a pressure control valve (Figure 1:199) capable of regulating pressure within the housing. Fahy, however, does not expressly indicate that the vent is configured to restrict the rate at which external pressure changes are transmitted to the inside of the portable housing.

Art Unit: 1797

Barbera-Guillem discloses a cell culture chamber in which a membrane (Figure 1:180) is provided for regulating gas diffusion to and from the interior of the chamber. Paragraph [0204] teaches that the membrane is fluid impervious and gas permeable. Paragraph [0207] states that the membrane is formed from a material capable of regulating the rate of gas diffusion regardless of the pressure of the gases in the external atmosphere.

Fahy and Barbera-Guillem are analogous art because they are from the same field of endeavor regarding cell culture systems.

At the time of the invention, it would have been obvious to equip the portable housing disclosed by Fahy with a membrane material capable of restricting the rate at which external pressure changes are transmitted to the inside of the portable housing. Barbera-Guillem teaches that cell cultures are sensitive to changes in pressure and the concentration of critical gases. Accordingly, it would have been obvious to allow pressure to vary within the housing of Fahy to between predetermined values known to be compatible with tissue storage. Furthermore, it would have obvious to provide the vent of Fahy with a membrane capable of regulating the rate of gas diffusion regardless of the pressure of the gases in the external atmosphere.

The combination of Fahy and Barbera-Guillem still differs from Applicant's claimed invention because Owen does not expressly state that more than one lid forms an airtight seal with the portable housing.

Hassanein discloses a device for storing and maintaining a tissue. The system includes a portable housing (Figure 2:20) sealed by a first lid (Figure 2:102) and a second lid (Figure 2:104). This is disclosed in column 10, line 66 to column 11, line 22. Hassanein teaches that both the first lid and the second lid each form a seal with the portable housing using a clamping ring (Figure 2:96).

Fahy and Hassanein are analogous art because they are from the same field of endeavor regarding organ perfusion, storage and transport devices.

At the time of the invention, it would have been obvious to provide the Fahy apparatus with first and second lids that are each include a pressure control valve, and are each capable of forming an airtight seal with the portable housing. The use of an additional lid would prove desirable because it would serve to discourage contamination by providing an additional barrier. Hassanein indicates that it is known in the art to utilize multiple lids comprising ports designed to interact with one another. As evidenced by Hassanein, one of ordinary skill in the art would have been able to use multiple lids to create an airtight seal with the portable housing of an organ perfusion device, such as that of Fahy, in a highly predictable manner using well known techniques.

With respect to claim 2, Fahy, Barbera-Guillem and Hassanein disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejections above. Although Fahy only describes the use of a single pressure control valve per lid, it would have been obvious to utilize a plurality of closeable vents per lid in this device. The

Art Unit: 1797

addition of extra venting mechanisms would involve no major structural reconfiguration of the Fahy device, and would require only a minor duplication of parts that are well known in the art. See MPEP 2144.04. Additional pressure control valves would result in a more uniform removal of gases from the organ maintenance system.

With respect to claims 4 and 11, Fahy, Barbera-Guillem and Hassanein disclose the apparatus in claims 1 and 9. Fahy further states that the portable housing includes a lid and the pressure control valve is arranged in the lid. This is apparent from Figure 1.

With respect to claim 6, Fahy, Barbera-Guillem and Hassanein disclose the apparatus in claim 1. Column 7, lines 39-56 of Fahy further indicates that the portable housing further comprises a pressure sensor (Figure 1:124) that is referenced to a desired pressure.

3) Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438) each in view of Barbera-Guillem (US 20040029266) and Hassanein (US 6953655), and further in view of Brasile (US 6582953).

Owen and Fahy each in combination with Barbera-Guillem and Hassanein disclose the apparatus set forth in the 35 U.S.C. 103 rejections above, however do not

Art Unit: 1797

expressly disclose that a pressure sensor is used to maintain the pressure inside the portable housing.

Brasile discloses an organ chamber transport system in which sensors are provided for determining a multitude of critical variables such as temperature, pH, pressure and flow rate. A microprocessor is used to correct the internal pressure based on detected measurements. This is disclosed in column 3, lines 47-60

Owen, Fahy and Brasile are analogous art because they are from the same field of endeavor regarding organ transport systems.

At the time of the invention, it would have been obvious to provide the Owen and Fahy systems with the means for continuously monitoring pressure within the tissue chamber. Brasile teaches that tissue cultures are sensitive to pressure changes, and that pressure detection means are necessary to maintain appropriate conditions. Brasile indicates that automatic control systems are especially beneficial means to monitor the tissue culture in real time.

4) Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Owen (WO 00/18226) or Fahy (US 5586438) each in view of Barbera-Guillem (US 20040029266) and Hassanein (US 6953655), and further in view of Eudailey (EP 0337677).

Owen and Fahy each in combination with Barbera-Guillem and Hassanein disclose the apparatus set forth in the 35 U.S.C. 103 rejections above, however do not expressly disclose that the pressure control valves include a hydrophobic membrane.

Eudailey discloses a portable housing for accommodating tissues. The lid (Figure 1:10) provided over the housing includes a plurality of pressure control valves (Figure 3:36) each capable of venting gases contained within the housing. Eudailey further states that a hydrophobic membrane (Figure 3:34) is positioned across the vents.

Owen, Fahy and Eudailey are analogous art because they are from the same field of endeavor regarding tissue culture systems.

At the time of the invention, it would have been obvious to provide hydrophobic membranes across the closable vents disclosed by Owen and Fahy. Eudailey teaches that hydrophobic membranes are beneficial because they serve to retain critical fluids within an organ container while allowing the escape of gases. Eudailey further states that membranes advantageously prevent microorganisms and other particulate contaminants from entering the interior of the tissue housing.

Response to Arguments

Applicant's arguments filed 05 March 2009 with respect to the 35 U.S.C. 112 rejections set forth in the previous Office Action have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 05 March 2009 with respect to the 35 U.S.C. 103 rejections involving Owen and Fahy each with Barbera-Guillem have been fully considered and are persuasive. Therefore, these rejections have been withdrawn.

Art Unit: 1797

However, upon further consideration, a new ground of rejection is made in view of the combination of Owen with Barbera-Guillem and Hassanein, as well as the combination of Fahy with Barbera-Guillem and Hassanein.

The Hassanein reference addresses the deficiencies of Owen and Fahy by indicating that it is known in the art to provide multiple lid members that each seal the opening of a portable housing. Hassanein indicates that it is known in the art to utilize multiple lids comprising ports designed to interact with one another. Since Owen, Fahy and Barbera-Guillem each indicate the importance of providing ports and pressure control means, one of ordinary skill would have been motivated to add a pressure control membrane to both the first and second lid of the modified Owen and Fahy devices.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1797

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN A. BOWERS whose telephone number is (571)272-8613. The examiner can normally be reached on Monday-Friday 7 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/

Primary Examiner, Art Unit 1797

/Nathan A Bowers/
Examiner, Art Unit 1797